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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,858	02/18/2005	Sadanobu Shirai	2005_0152A	3564

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EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
01/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,858	SHIRAI ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicants' response, which was filed on 29 October 2007.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,117,447 ("Nakano").

Nakano teaches a percutaneous patch formulation (*see* col. 2, lines 7-11). The disclosed patch is comprised of:

- an adhesive layer on a backing (*see* col. 2, lines 13-16);
- said adhesive layer comprising:
  - tulobuterol (*see* col. 2, line 67);
  - C_{11}-C_{22} fatty acids (*see* col. 2, lines 49-54);
  - rubber (*see* col. 2, line 48);
  - adhesive resin, *e.g.* petroleum resin (*see* col. 4, lines 41-42); and
  - plasticizer, *e.g.* polyterpene resin (*see* col. 4, line 42).

Nakano explains that combining the disclosed agents into a patch formulation is beneficial because it results in "superior percutaneous absorption of the drug." (*see* col. 3, lines 4-12).

While Nakano does not explicitly teach all the instantly claimed percentages, it is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined tulobuterol, a rubber, an adhesive resin, a higher fatty acid, and a plasticizer into a patch formulation, as taught by Nakano. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a formulation because it results in superior percutaneous absorption of tulobuterol, as explained by Nakano.

* * * * *

Response to Arguments

Applicants' arguments filed 29 October 2007 have been fully considered but they are not persuasive.

1. Applicants argue that, "...the content of tulobuterol contained in an adhesive layer is different from each other, namely the preparation of the present invention relates to one containing a lower concentration of tulobuterol (1 to 4 w/w%), and the preparation disclosed in Nakano et al. relates to one containing a higher concentration of tulobuterol (not less than 5 wt %)." *See* response, page 2.

Nakano states explicitly that patch formulations using a concentration of tulobuterol within the range claimed instantly (i.e. 3 wt %) are known in the art (*see* col. 3, lines 24-26.) Nakano discloses a tulobuterol concentration of 5 wt % (*see* col. 3, lines 30-33) while the instant application claims a tulobuterol concentration of up to 4 wt % (*see* claim 1). A prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). *See* MPEP 2144.05.

2. Applicants argue that, "[a]s shown in Table 1 and Figure 3 of the present application, the patch of Nakano et al. is far inferior to the patch of the present invention (a patch of Example 1) in drug permeability." *See* response, page 4.

Examiner respectfully submits that the data presented at Table 1 and Figure 3 do not accurately reflect the scope of what applicants are claiming. Table 1 compares Comparative Example 6 which contains 5 w/w% tulobuterol with Example 1 which

contains 2 w/w% tulobuterol. However, applicants are claiming a concentration which is up to two times the concentration used in Example 1, i.e. 4 w/w%. Applicants provide no comparison data between a patch formulation with 4 w/w% tulobuterol, and one with 4 w/w% tulobuterol. Thus, examiner respectfully submits, applicants have not shown any unexpected results between what is being claimed and the prior art.

3. Applicants argue that, "...the preparation of the present invention contains a higher fatty acid...as a drug-release controlling agent as an essential component, but the preparation disclosed in Nakano et al. does not contain such a fatty acid, but rather, contains a fatty acid ester such as isopropyl myristate as a solublilizer..." Emphasis removed. *See* response, page 2.

Examiner respectfully submits that the term "fatty acid", as used in the art, includes fatty acid esters; applicants have not given a special definition to the term which would remove fatty acid esters from said definition. Fatty acids consist of a lipid portion and an acid portion. The fatty acid esters disclosed by Nakano contain an acid portion (*e.g.* an ester of a dibasic acid having 6 to 10 carbon atoms, *see* col. 2, lines 53-55), as well as the lipid portion of up to 16 carbon atoms (*see* col. 2, lines 52-53).

Tulobuterol binds non-covalently to the lipid portion of the fatty acid, which in turn functions as a drug controlling agent. The lipid portion of the fatty acid ester disclosed by Nakano is identical to that claimed (*i.e.* up to 16 carbons). Thus, examiner respectfully submits that the fatty acid ester disclosed by Nakano will have the same physical property as the fatty acid instantly claimed, i.e., it will act as a drug controlling agent.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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HUMERA N SHEIKH
PRIMARY EXAMINER